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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09-494,088	01/28/2000	Michael McGrogan	L01-06CIP	3025

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/21/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/494,088

Applicant(s)

MCGROGAN ET AL

Examiner

Anne-Marie Falk Ph D

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

- 1 ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
- 2 ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

- 3 ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
- 4 ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- 5 ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- 6 ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- 7 ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-17 and 19-24

Claim(s) withdrawn from consideration: _____

- 8 ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
- 9 ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 21.
- 10 ☐ Other: _____

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit 1632

Art Unit: 1632

Continuation Sheet (PTO-303)

Continuation of 3. Applicant's reply has overcome the following rejection(s):
the rejections of Claims 2-5 and 24 under 35 U.S.C. 112, second paragraph.

Continuation of 5. The Declaration and request for reconsideration has been considered but does NOT place the application in condition for allowance because:

The Declaration of Dr. McGrogan has been fully considered but is not deemed persuasive. The Declaration points to the reference of Baker et al. (2000) at pp. 354-355 where it states that "[o]nly animals that had surviving THir cells (43% of the hNT-DA group and the LiCl pretreated hNT-DA group) had increased rotational scores while animals with no THir cells (hNT-neuronal grafts and lesion only groups) did not exhibit any reduction in mean full body turns (**Fig. 6**)" (emphasis added). However, the legend to Figure 6 states that "[a]lthough a reduction of rotational behavior was observed in the hNT-DA neuron and LiCl pretreated hNT-DA neuron groups, this reduction did not achieve statistical significance." Furthermore, the reference states at page 354, "[i]n animals maintained for 6 weeks with double grafts of either hNT-DA neurons or LiCl pretreated hNT-DA neurons rotational behavior exhibited a trend toward decreasing rotations, but this did not reach statistical significance." The abstract of the reference states,

"THir cells were observed in 43% of animals with hNT-DA neuronal grafts and all animals with LiCl pretreated hNT-DA neuronal grafts (100%). The number of THir neurons in these animals was low and not sufficient to produce significant functional recovery."

At page 358, column 1, paragraph 2, the reference states "[t]he failure of hNT neurons to provide functional recovery in the present study may relate to the relatively low number of THir neurons and poor fiber outgrowth observed in surviving grafts." Given these statements it is evident that the Baker et al. reference discloses no more than Example 12 of the instant specification, which demonstrates that the experiments performed did not result in functional recovery as the reduction in rotational behavior of the rats was not statistically significant (specification at top of page 30).

Thus, the rejection of Claims 1-17 and 19-24 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained for reasons of record.